BQC-93-055

Date: September 9, 1993

BQC-93-055
To: End Stage Renal Dialysis Facilities ESRD 7

From: Judy Fryback, Director
Bureau of Quality Compliance

Subject: FDA Safety Alert

On August 19, 1993 the FDA issued a safety alert dealing with fluoride contamination of hemodialysis water supply to Hemodialysis Personnel and Water or Dialysate Service Contractors. A copy of the alert has been enclosed for your information. Please review this information and take all necessary precautions to ensure that this type of situation does not occur at your facility.

Please share this information with the appropriate staff. Direct any questions you may have to Stephen D. Schlough, Chief, Hospital and Health Services Section, Bureau of Quality Compliance at the above indicated address or telephone him at (608) 266-3878.

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cc: -BQC Staff
-Office of Legal Counsel
-Ann Haney, DOH Admin.
-Kevin Piper, BHCF Dir.
-HCFA, Region V
-Illinois State Agency
-Ohio State Agency
-Michigan State Agency
-Indiana State Agency
-Minnesota State Agency
-WI Hospital Association
-Commission on Geriatric Health
-Non-LTC BQC Memo Subscribers
-Renal Dialysis Network 11

Department of Health & Human Services
Public Health Service
Food and Drug Administration
Rockville MD 20857

FDA SAFETY ALERT:
FLUORIDE CONTAMINATION OF HEMODIALYSIS WATER SUPPLY

TO: Hemodialysis Personnel and Water or Dialysate Service Contractors August 19, 1993

This is to alert you to a recent incident in which three hemodialysis patients died and several others were hospitalized after exposure to high levels of fluoride in their dialysate, and to urge that you take certain precautions to prevent other incidents of this kind. Please share this Safety Alert with those within your organization who are responsible for water treatment, dialysate delivery systems (including water treatment systems), and patient care.

In the incident, which was investigated by the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC), the fluoride concentration in the dialysate was reported to be 15-25 ppm; the ANSI/AAMI standard identifies 0.2 ppm as the acceptable level of fluoride in dialysate.

The high concentrations occurred because the deionizer used to remove fluoride and other contaminants had become exhausted. Part of the problem may have been the warning lights on the deionizer tanks which are used to alert personnel that the deionizer is exhausted. The previous model at the facility used a single light to indicate that the system was functioning properly; when the light went out, the system was nearing exhaustion and needed replacement or regenerating.

The newer deionizer model recently installed at the facility used a different style warning system with two lights: a green one to indicate that the system is functioning normally, and an amber one to indicate that it needs recharging. This change could have caused confusion and contributed to the problem. FDA is continuing to investigate the situation.

In the meantime, we recommend the following precautions:

- If you are using deionizers in your water system, be sure that their sensitivity monitors have <u>both</u> visual and audible warning systems to alert personnel that the resin is approaching exhaustion. This is specified in the ANSI/AAMI Standard.[1]

- Be sure that dialysis staff are adequately trained in the proper operation of your water treatment system. <u>It is particularly important that they understand the use of the monitoring and warning system.</u> If you do not have sufficient information to train the staff, contact your manufacturer/ supplier.

- If re-design, modify or buy a new water system, be sure that any existing pre-treatment or other component is compatible with the new system.

For further guidance on hemodialysis water systems, please refer to the FDA publication entitled "A Manual on Water Treatment for Hemodialysis." This document may be purchased from the National

[1] American National Standard, ANSI/AAMI RD5-1992, Hemodialysis Systems, p. 6.

Association of Nephrology Technologists, 60 Revere Drive, Suite 500, Northbrook, IL, 60062, FAX (708) 480-9282.

Please remember that deaths, serious illnesses and injuries associated with the use of medical devices, including dialysis equipment, must be reported to FDA or to the manufacturer. You may report such incidents by phoneing 301-427-7500, by FAXing 301-881-6670, or by writing FDS, CDRH, MDR User Reporting, P.O. Box 3002, Rockville, MD, 20847-3002.

For further information about this Safety Alert, you may contact: A.W. Thomas, FDA, HFZ-250, Rockville, MD, 20857, FAX 301-443-8810.

This incident underscores the need to continuously monitor the water quality in hemodialysis systems. I urge you to verify that your dialysis water is safe and that you have an adequate continuous monitoring system in place.

Sincerely yours,

/s/ D. Bruce Burlington, M.D.
Director
Center for Devices and Radiological Health